Remarks in Support of Patentability

Rejection Under 35 USC 112

Claims 1-10, 24 and 25 were rejected under 35 USC 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention.

Specifically, Claims 1, 24 and 25 were objected to due to the inclusion of the phrase "chimeric protein¬encoding portion of the recombinant polynucleotide is protected by a binding moiety which is a protein ...". The earlier amendment to the claim to overcome this objection was rejected for being a process limitation. Accordingly, these claims have been amended to recite that the "binding moiety which is a protein and which is bound non-specifically to the polynucleotide irrespective of nucleotide sequence" and further to specify that "the nucleotide binding protein of the chimeric protein is bound to the nucleotide sequence motif of the recombinant polynucleotide" as suggested by the Examiner in the Office Action. As amended the claims clearly refer to features of the construct per se. The Examiner's attention is drawn to lines 11 and 12 of Claims 24 and 25 which state that the "nucleotide sequence motif which is specifically bound by the nucleotide binding portion" of the chimeric protein. A corresponding amendment has been made to Claim 6.

Rejection Under 35 USC 102(b) and 35 USC 103(a)

Claims 1, 3-6, 8-10 and 25 were rejected as being anticipated by or obvious over US 5,498,530 (Schatz).

The construct described by Schatz is a chimeric protein bound to a recombinant double stranded DNA vector. The chimeric protein includes a DNA binding portion and a target peptide.

It is particularly noted that Schatz refers only to a double stranded DNA vector. As amended, the claims of the application in suit are directed to a sinqle stranded polynucleotide. Basis for this amendment may be found on page 11, lines 1 to 6.

Schatz does not suggest that the double stranded DNA vector present in the construct described should be protected from degradation in any way. By contrast, in the application in suit, the single stranded polynucleotide is protected by a binding protein which is bound to the chimeric protein-encoding portion of the recombinant polynucleotide not bound by the nucleotide binding portion of the chimeric protein. Thus, in the construct claimed in the present invention the recombinant polynucleotide is bound by the chimeric protein and also by the binding protein. No such binding protein is present in the construct of Schatz, nor does Schatz even recognize the possibility of including such a binding protein.

In the Office Action, the Examiner had suggested that although the vector used by Schatz (plasmid vector pMC5, shown in Figure 2) clearly lacks a gene encoding for functional viral coat protein, nonetheless the reference to the use of recombinant vectors which would include a phage (column 4, lines 44 to 50) and that the use of both phage and plasmid fusions to increase the total available peptide diversity (see column 21, lines 46-60) would overcome this deficiency. It is submitted that the Examiner has taken the reference to "phage" on column 4, line 47 of Schatz out of context and has used ex post facto analysis to assume expression of a viable coat protein able to bind to the construct of Schatz. The reference to "phage" on column 4, line 47 of Schatz clearly cannot be to a complete phage on the basis that a wild type phage would not encode chimeric protein of interest to Schatz. Consequently, the reference to "phage" in this context is to its use as the starting material for a phage vector. Only a phage vector could be manipulated to encode the chimeric protein of interest to Schatz and one of ordinary skill in the art would read

the reference to "phage" in column 4, line 47 as being to a phage vector. Schatz never refers to a phage vector able to encode a viable coat protein and provides no examples of any such vectors. One of ordinary skill in the art would be aware that the gene for the coat protein is routinely deleted in a phage vector to provide a location for the insertion of exogenous genes of interest. Consequently, there is no reference whatsoever to the possibility of the Schatz construct being bound by a binding protein as required in application in suit.

The reference to phage fusions in column 21 of Schatz is contrasting these to a preferred embodiment of the Schatz construct, the lac repressor fusions. The paragraph states that "there is no need ... to be compatible with the protein export apparatus and the formation of an intact phage coat". In other words, Schatz clearly teaches that an intact phage coat is not required.

In conclusion, the construct of Schatz differs from that claimed in the instant application since the Schatz construct is not packaged into a PDCP, with the target peptide portion displayed externally on the package. Further, the Schatz construct comprises only double stranded DNA. Further, the Schatz construct does not have a protein binding moiety bound to the polynucleotide. The claims as amended are clearly novel over Schatz.

As stated above, the advantages of having the chimeric protein encoding portion of the polynucleotide bound by a protein binding moiety is not recognised by Schatz.
As a consequence, nuclease degradation of the DNA vector of the Schatz construct would occur and would reduce the yield of the construct. This disadvantage is overcome in the present invention where the construct claimed includes a binding moiety bound to the polynucleotide.

Furthermore, the construct of Schatz can only be released upon lysis of the host cell (see column 2, lines 53-56 of Schatz). By contrast, the present invention claims a synthetic construct which is a peptide display carrier package. One of the properties of the peptide display carrier

package as claimed in the application in suit is its ability to be extruded from the host cell without lysis of the host cell. This has a very significant advantage for obtaining pure PDCP and this advantage is not anticipated in any way by the teachings of Schatz.

The Examiner also objected to Claims 1, 3-10 and 24-25 as being obvious over a combination of Schatz and US 6,451,527 (Larocca). The Examiner argued that Schatz teaches the use of different DNA binding proteins, including nuclear hormone receptor type proteins and Larocca teaches the use of altering the phage genome by incorporating DNA binding proteins. In the Examiner's view, it would have been obvious to one skilled in the art to use steroid receptor proteins in the phage vector system. However, the teachings of Schatz and Larocca cannot be combined in the manner suggested by the Examiner. Specifically, inserting steroid receptor proteins into the phage vector system of Larocca would not result in a construct as claimed in the current application. It is noted that both Larocca and Schatz rely upon double stranded DNA vectors. Thus, a combination of these documents would not result in a construct having a single stranded polynucleotide as claimed in the present application. Also, as stated above, Schatz fails to suggest the use of a binding protein as part of the construct produced. Similarly, Larocca states that the methodology used involves "recovery of uncoated phage" (see column 13, line 40). Accordingly, Schatz fails to teach the use of a binding protein and Larocca specifically teaches against use of such a protein. Combination of these references would therefore not result in a construct as claimed in the application in suit. Further, one skilled in the art would not consider the combination of the Schatz and Larocca references on the basis that the methodology described by Schatz is limited to bacterial cells, whereas that described by Larocca requires mammalian (eukaryotic) cells.

Even in combination, Schatz and Larocca do not suggest a PDCP as now claimed, nor do these documents suggest a PDCP in which the fusion protein is expressed on the surface and the polynucleotide not bound by the chimeric protein is protected from degradation by a binding protein.

Applicant believes that the application is now in condition for allowance and respectfully requests the issuance of a Notice of Allowance.

To the extent there is any fee required in connection with the receipt, acceptance and/or consideration of this paper and/or any accompanying papers submitted herewith, please charge all such fees to Deposit Account 50-1943.

Respectfully submitted,

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I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date indicated below, with sufficient postage, as first class mail, in an envelope addressed to: Mail Stop: Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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